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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/598,975

09/15/2006

David I. Cohen

51311-00008

2799

45200 7590 09/16/2008
K&L Gates LLP
1900 MAIN STREET, SUITE 600
IRVINE, CA 92614-7319

EXAMINER

PARKIN, JEFFREY S

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

09/16/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/598,975	Applicant(s) COHEN, DAVID I.	
	Examiner Jeffrey S. Parkin, Ph.D.	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 10-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06 June, 2007</u> . | 6) <input type="checkbox"/> Other: _____ |

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Detailed Office Action

Status of the Claims

Acknowledgement is hereby made of receipt and entry of the communication filed 19 June, 2008. Applicant's election of Group I (claims 1-9) is noted. Because applicant did not distinctly and specifically point out the purported errors in the restriction requirement, the election has been treated as an election without traverse (refer to M.P.E.P. § 818.03(a)). Claims 10-17 are withdrawn from further consideration by the examiner, pursuant to 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

37 C.F.R. § 1.98

The information disclosure statement filed 06 June, 2007, has been placed in the application file and the information referred to therein has been considered.

35 U.S.C. § 119(e) or § 120 Benefit

Applicant is advised that the first sentence(s) of the specification following the title should be updated to reflect the status (e.g., abandoned or patented) of all applications relied upon under 35 U.S.C. § 120, 121 or 365(c). Appropriate amendments should be performed.

Perusal of prior applications 10/456,865, filed 06 June, 2003, and 09/636,057, filed 08 August, 2000, failed to provide support for the currently claimed invention. Accordingly, for the purposes of applying prior art under 35 U.S.C. § 102 or §

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103, the effective filing date will be that of provisional application no. 60/553,733, filed 16 March, 2004.

35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 9 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Wang *et al.* (2002). The claims are broadly directed toward any Tat-based vaccine composition comprising an antigen coupled to at least one Tat molecule. Wang and colleagues disclose the preparation and administration of a Tat-TRP2 vaccine composition. This composition afforded complete protection in murine hosts. Clearly, this teaching meets all of the claimed limitations.

35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode

contemplated by the inventor of carrying out his invention.

Scope of Enablement

Claims 1-9 are rejected under 35 U.S.C. § 112, first paragraph, because the specification specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The claims are broadly directed toward a Tat-based vaccine composition comprising at least one antigen coupled to at least one lentiviral Tat molecule. The claims are not limited by their target host and could include human, as well as, veterinary vaccines. The disclosure provides a single working embodiment wherein a Tat-HPV E7 fusion protein appeared to afford protection in a murine host. Appropriate amendment of the claim language to reflect this example would obviate the rejection.

The legal considerations that govern enablement determinations pertaining to undue experimentation have been clearly set forth. *Enzo Biochem, Inc.*, 52 U.S.P.Q.2d 1129 (C.A.F.C. 1999). *In re Wands*, 8 U.S.P.Q.2d 1400 (C.A.F.C. 1988). *Ex parte Forman* 230 U.S.P.Q. 546 (PTO Bd. Pat. App. Int., 1986). The courts concluded that several factual inquiries should be considered when making such assessments including the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art and the breadth of the claims. *In re Rainer*, 52 C.C.P.A. 1593, 347 F.2d 574, 146 U.S.P.Q. 218 (1965). The disclosure fails to provide adequate

guidance pertaining to a number of these considerations as follows:

1) The disclosure fails to provide adequate guidance pertaining to the identification, characterization, and selection of suitable protective/therapeutic cancer/infectious disease antigens for inclusion in the Tat-based vaccine. In order to practice the claimed invention with any confidence, the clinical practitioner would require a knowledge of the immunogen being administered. The disclosure is silent concerning this caveat.

2) The disclosure fails to provide adequate guidance pertaining to suitable vaccine compositions/formulations, adjuvants, modes of administration, and immunization regimens. In order to practice the claimed invention, the skilled clinician would need to know the proper site/route of administration (i.e., oral, intramuscular, subcutaneous, mucosal, etc.) and immunization regimen. However, the disclosure fails to provide sufficient guidance pertaining to these concerns.

3) The prior art teaches that vaccine development for both cancer and infectious diseases has been extremely difficult (Dalglish and Whelan, 2006; Harrop *et al.*, 2006; Walker and Burton, 2008). Cancer vaccines have suffered from a number of limitations because of a failure to identify suitable cancer immunogens, formulations, and appropriate immunization regimens. The inability to target the immune response to the tissue of interest has also been limiting. Moreover, many cancers are quite adept at evading the host immune response. Accordingly it is imperative that the proper cancer immunogen be identified. Animal models for clinical vaccine evaluation have also proved problematic. Concerning infectious diseases, several problems have led to vaccine failure including a lack of understanding of

the correlates of human protection, a lack of understanding of suitable protective immunogens, vaccine formulations, adjuvant selection, and immunization regimens, the ability of many viruses to exist as a quasispecies thereby leading to immune evasion/escape, and the failure of many animal models to adequately assess vaccine efficacy.

4) The disclosure fails to provide a sufficient number of working embodiments to enable the full breadth of the claimed invention. Considering the unpredictability associated with the fields of cancer/infectious disease vaccine development, it would certainly require more than a single working embodiment to enable the full breadth of the patent protection desired.

5) The claim breadth is excessive and fails to limit the vaccine of interest to any particular cancer or infectious disease immunogen. The disclosure fails to provide a sufficient number of working examples and guidance to enable the full breadth of the protection desired.

Accordingly, when all the aforementioned factors are considered *in toto*, it would clearly require undue experimentation from the skilled artisan to practice the claimed invention.

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Bruce R. Campell, Ph.D., can be reached at (571) 272-0974. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

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Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related correspondence to be: a) faxed to the Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or delivered to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing System. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information refer to the Updated Notice of Centralized Delivery and Facsimile Transmission Policy for Patent Related Correspondence, and Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

/Jeffrey S. Parkin, Ph.D./
Primary Examiner, Art Unit 1648

06 September, 2008